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**APPLICATION FOR LETTERS PATENT**

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**CLOTHING APPARATUS, CARRIER FOR A  
BIOPHYSICAL SENSOR, AND PATIENT ALARM  
SYSTEM**

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**CLOTHING APPARATUS, CARRIER FOR A BIOPHYSICAL SENSOR, AND  
PATIENT ALARM SYSTEM**

**CROSS-REFERENCE TO RELATED APPLICATIONS**

**[0001]** This application claims the benefits of U.S. Provisional Patent Application Serial No. 60/244,400 filed October 30, 2000 and which is incorporated by referenced herein.

**TECHNICAL FIELD**

**[0002]** This invention relates primarily to remote monitoring of newborn infants in their mother's convalescent room. A sensor unit placed in direct skin contact on the chest over the infant's heart senses infant skin temperature, chest sound, and reflectance pulse oximetry. Radio telemetry and computer network technology is used to communicate data from the sensor unit to a data processing and display system, and to locate and confirm the presence of the infant within the facility.

**BACKGROUND OF THE INVENTION**

**[0003]** Single-Room Maternity Care (SRMC) is the maternity care process for which the present system is developed. During the normal infant transition period of from 3 to 24 hours, SRMC babies are held for feeding and socialization in the mother and father's arms, are passed from one person to another, and are placed to rest in an infant-warming bassinet; all within the mother's post-partum convalescent room. When the new family is alone, the SRMC nurse needs to be able to routinely check on the baby without having to disturb the baby, or even

enter the room. Disturbance of the family for unnecessary routine medical data recording and use of obtrusive medical technology must be avoided. An infant patient sensor probe, remote communications, and data display means is needed to support this care process by safely and effectively monitoring the infant for temperature stability and signs of distress or illness.

**[0004]** The prior art for safe and effective monitoring of newborn infants during transition uses manual, low technology, or wire-connected, high-technology "intensive care-style" methods. Low technology methods include a thermometer held under the infant's arm, or placed into the rectum, to measure body temperature. If a servo-controlled infant warming system is used, a thermistor on the end of a cable is typically taped to the infant's skin to monitor temperature and control the warmer heat output.

**[0005]** An acoustic stethoscope placed on the infant's chest is the common means of listening to heart and lung sounds to measure heart rate and breathing rate. However, the contact and movement of the stethoscope is disturbing to the infant and, while not painful, may disrupt needed sleep or detract from family social interaction time. Prior art acoustic and electronic stethoscopes are not configured for continuous, automated infant monitoring. The operator must directly listen to, and mentally interpret, the output sound signal from the electronic system. Heart rate and breathing rate may be continuously monitored using an intensive care-style three-chest-lead ECG and respiration monitor system. However, neither means can detect obstructed breathing during deep sleep.

**[0006]** Oxygen saturation of circulating arterial blood hemoglobin can be grossly evaluated by visual inspection of the infant's skin color. Oxygen

saturation can be measured much more sensitively and accurately by analysis of an arterial blood sample. A slightly less accurate, but non-invasive, means of blood oxygen monitoring is the application of an opto-electronic pulse oximeter probe to a hand or foot of the infant. Prior art pulse oximeters adapted for use with infants connect the patient-contact probe with the main electronics and display console by means of a cable. Most devices are "transmission" style oximeters, in that they emit light into the tissue on one side of a body part, such as a foot, and detect the variably absorbed light on the opposite side. An available adult size finger "clip-on" transmission oximeter and pulse rate monitor runs on replaceable common batteries and is self-contained. This latter device is not designed for application on infants, must be directly viewed to obtain data, cannot be adequately cleansed between patient uses, and does not include means of monitoring skin temperature or breathing.

**[0007]** Recent oximeter designs use "reflectance" style probes, which detect the diffused light in the tissue on the same surface as, but at some lateral distance from the emitter. Specifically, one of several patented reflectance mode oximeter probes is now used as an adjunct to fetal monitoring during labor. This probe, mounted on the end of a stiff cable, is passed through the mother's cervix, bringing the optical system of the probe into direct contact with the skin surface of the fetus. While this has been demonstrated to be successful in the very low ambient light condition of the womb, the use of reflectance mode oximetry using red and infrared light has previously been problematic with infants following birth under normal ambient light levels.

**[0008]** Prior art measurement of infant skin temperature comprises either intermittent, manual measurement with either a traditional glass, or an electronic

thermometer; or use of a cable-attached electronic sensor. The presence of a temperature control sensor wire, a pulse oximeter cable, and/or ECG leads and cable applied to an infant, connotes in the lay public's mind a condition of medical concern or problem. In the case of most normal newborn infants, such a message is not warranted or intended.

**[0009]** The prior art for security of infants in hospitals commonly includes tags in the form of wrist or ankle bands with written or bar code identification markings. Prior art also includes miniature radio transponder or magnetized tags for attachment to the infant's umbilical clamp, or integrated with wrist or ankle bands. Departure of the infant wearing such a device through a secured exit will trigger the alarm. These devices typically operate by having a surveillance sensor apparatus mounted at all exits to either poll the transponder tags, or scan for magnetic tags. Prior patents claim use of a wrist or ankle band, which, if torn or cut, will trigger an alarm when polled by the surveillance system. However, no prior art continuously identifies the location of the infant in the care facility during routine, normal care. There is also no prior art for infant security means that derive physiologic data confirming the infant's living presence in conjunction with the tag or transponder. Thus, these prior forms of infant security may be frustrated if the tag or band can be removed from the infant in such a way as to avoid damage to the tag or band. Simply not damaging the band, or not passing the tag through the exit sensor, avoids setting off the alarm, allowing the untagged infant to leave undetected.

**[0010]** Single-Room Maternity Care (SRMC) is the desired optimum care process for mothers and babies following normal, uncomplicated hospital-based childbirth. An improvement is needed to provide new families the option of being

continuously and directly involved during this newborn transition period without compromising the quality of the medical surveillance of the infant's health.

**[0011]** One advantage of the present invention is to improve the quality and quantity of time with infant and parents privately together following birth;

**[0012]** Another advantage of the present invention is to ease and safety in sanitizing a clothing article and a sensor for re-use, in a manner that is also reliable.

### **SUMMARY OF THE INVENTION**

**[0013]** The Single-Room Maternity Care (SRMC) health care process model needs an automated and remote means of monitoring basic vital signs of healthy newborn infants during their transition period. This means must not distract from the social interaction of the family, and must not convey a message of over-concern for apparently well infants. Continuously tracking the location and physical security of infants also needs to be provided by an unobtrusive, but highly reliable means. Reduction in the skilled manual tasks required, and in the numbers of nursing staff, are additional economic benefits of the desired system of infant monitoring in the SRMC setting.

**[0014]** An integrated system is presented for routine, remote, lead-less vital sign monitoring of newborn infants during transition in the SRMC process. The infant patient sensor unit is a hermetically sealed, smooth "pebble-shaped" device, which is retained in a sewn pocket of a modified infant undershirt. Skin temperature, chest sound, and reflectance-mode pulse oximetry signals are obtained and initially processed by this battery-supplied sensor unit. The resulting "raw" data is transmitted by half-plex radio transmission to ceiling-mounted transceiver/computer network interface modules. A central nursing

station computer server and color graphic terminal further processes the individual infant sensor-derived data, and numerically and graphically displays the derived vital information regarding each infant for clinical evaluation and security location. Nurses carry hand-held, wireless network computer data management units as they care for mothers and babies together. These units provide alarm "beeper," data display and evaluation, optional remote listening to infant chest sound, and chart recording capability.

**[0015]** An alternative embodiment of the present invention is the substitution of the computer network and central processor with a portable radio transceiver and data processor unit carried by the infant's caregiver in the ambulatory setting. This embodiment is intended to meet the needs of infants convalescing from premature birth and those who may be at risk for Sudden Infant Death Syndrome (SIDS).

**[0016]** Possible other applications include monitoring and tracking child and adult patients who may wander away from caregivers or whose health condition requires remote physiologic monitoring to help enable independent living. The lead-less configuration of the present invention makes it broadly suitable for a variety of such health- and security-related uses. Additionally, athletes may wish to use the ambulatory system to continuously and remotely log heart rate, breathing rate, temperature, and pulse oximetry as they exercise and perform. An alternate means of positioning and stabilizing the sensor unit will, of course, accompany this latter application.

## **BRIEF DESCRIPTION OF THE DRAWINGS**

**[0017]** Preferred embodiments of the invention are described below with reference to the following accompanying drawings.

**[0018]** Fig. 1 is "Virtual Nursery" infant monitor system.

**[0019]** Fig. 2 is optional ambulatory data processing system.

**[0020]** Fig. 3 is infant undershirt detail.

**[0021]** Fig. 4 is chest sound and skin temperature sensors.

**[0022]** Fig. 5 is reflectance oximeter sensor.

**[0023]** Fig. 6 is radio transceiver and battery power system.

## **DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS**

**[0024]** This disclosure of the invention is submitted in furtherance of the constitutional purposes of the U.S. Patent Laws "to promote the progress of science and useful arts" (Article 1, Section 8).

**[0025]** Reference will now be made to a preferred embodiment of Applicant's invention. An exemplary implementation is described below and depicted with reference to the drawings comprising a virtual nursery monitoring system including a clothing apparatus. While the invention is described by way of a preferred embodiment it is understood that the description is not intended to limit the invention to such embodiment, but is intended to cover alternatives, equivalents, and modifications which may be broader than the embodiment, but which are included within the scope of the appended claims.

**[0026]** In an effort to prevent obscuring the invention at hand, only details germane to implementing the invention will be described in great detail, with



presently understood peripheral details being incorporated by reference, as needed, as being presently understood in the art.

**[0027]** An integrated system is presented for routine, remote vital sign monitoring of newborn infants during transition. The lead-less infant sensor unit is a hermetically sealed, smooth "pebble-shaped" device. This sensor unit is retained in a sewn pocket of a modified infant undershirt. Skin temperature, chest sound, and reflectance-mode pulse oximetry signals are obtained from direct skin contact with the patient, and partially processed by this battery-supplied sensor unit. The resulting data is transmitted by radio transmission to ceiling-mounted transceiver/computer network interface modules. A central nursing station computer server and graphic terminal further processes the individual infant sensor-derived data for graphic display, recording, and research. Nurses carry hand-held, wireless network computer data management units as they provide direct care for mothers and babies. The network telemetry system locates individual infants within the facility. Security measures include alarms with loss of sensor contact with the patient, and with the departure of a patient sensor unit from the transmission range perimeter of the facility. The security alarm will graphically display the most recent location of the sensor unit to aid in initial tracking of a possible infant abduction. An ambulatory embodiment uses a portable, battery-powered data processing and display unit worn in a belt-pack by the infant's caregiver. This embodiment provides local display and alarms regarding the physiologic status of the infant, as well as a distance perimeter security alarm. The ambulatory data processing unit may also be connected to a telephone line for modem transmission of stored data to a remote site for analysis and corresponding expert advice to the caregiver.

## **[0028]**      Reference Numerals in Drawings

10 = patient contact sensor (physiologic data sensing apparatus)  
20 = sensor unit positioning system  
30 = infant undershirt  
40 = half-plex radio communication  
50 = radio transceiver and computer network interface module  
60 = central computer network server and color graphic terminal  
70 = sensor unit re-charge and test module  
80 = "palm-top" data management unit  
90 = printer for paper records of the graphic diagrams and clinical record text  
100 = archive computer media recorder  
110 = ambulatory transceiver, data processor, data display, and alarm output unit  
120 = elastic fabric band around infant undershirt  
130a,b = Velcro<sup>TM</sup> closure of sensor unit pocket  
140 = sensor unit positioning pocket  
150 = ambient light barrier fabric  
160 = opening for exposure of active surface of sensor unit to patient's skin  
200 = stethoscope diaphragm  
210 = piezoelectric vibration and sound transducer  
220 = stethoscope diaphragm to transducer coupling post  
230 = skin temperature sensor  
240 = flexible circuit to temperature sensor  
300a,b = oximeter LED's  
310 = oximeter projection light guide  
320 = projected light diffusing in patient's skin  
330 = optically interacted light within patient's skin and blood vessels  
340 = condenser rod lens (1 ea. / linear array segment)  
350 = focal plane light detector (1 ea. / linear array segment)  
500 = data communications antenna  
510 = sensor unit battery  
520 = battery re-charge power transmission antenna  
530 = metallic circuit cover  
540 = plastic shell

550 = metallic base frame

**[0029]** The infant skin contact sensor of the present invention is placed within the infant's clothing and blankets and is "out-of-sight" of the new parents. Normal social interactions are unimpeded while fully adequate monitoring functions are provided. This system is also compatible with simplified mattress warming systems, and with the administration of oxygen supplementation of the breathing gas, allowing all commonly applied infant transition medical functions to be performed in the mother's convalescent room. Holding, feeding, and passing the infant from one caregiver to another are not encumbered by monitor wires and cables which are sometimes used with normal and slightly distressed infants in their transition period. The sum total of these procedural advantages is a much less disturbing and troubling social impression to the already worried new parents.

**[0030]** Basic physiologic parameters needing to be monitored during newborn transition include: 1 heart rate, 2 breathing rate and depth, 3 skin temperature, and 4 arterial blood oxygenation. A means of unobtrusively performing these monitor tasks without the application of lead wires or adhesive contact pads to the infant is desired.

**[0031]** The present invention biophysical sensor probe is placed within a sewn pocket of a modified infant undershirt, with the active surface of the sensor in dry, direct contact with the infant's anterior chest skin, over the heart. Chest sound and skin temperature from this location is detected and transmitted by radio telemetry to a remote data processor and display system. Reflectance pulse oximetry is performed by the novel use of selected wavelengths of light; also with data transmitted to a remote site for final processing and display. The

net effect is the elimination of monitor lead wires and adhesive contact pads, and/or the need to repeatedly perform manual "vital sign" checks on the infant.

**[0032]** Identity, physiologic stability, and physical security of infants in the hospital birth setting comprise the major infant-related concerns in the post-childbirth care process. The present invention provides an inconspicuous, inherently secure, and reliable means of infant identification and location within the SRMC facility. Loss of biophysical signal, resulting from removal of the sensor unit from the infant's clothing, will generate an alarm and indication of the present location of the sensor unit. Removal of the infant, with its assigned sensor unit attached, from the SRMC area will be detected as a loss of response of the sensor unit to computer network polling; again generating a security alarm. In this latter scenario, the last known location of the sensor unit is held in memory to assist in immediately identifying the most recent location of the infant.

**[0033]** The patient contact sensor portion of the present invention is preferably embodied in a seamless, smooth, hard-surfaced case without connectors, lead wires, cables, or flexible-to-rigid material interfaces. Limited tolerance to being dropped needs to be provided by rigid internal encapsulation of critical components. Reasonable care of the present invention sensor unit will assure a high degree of reliability of the present invention in normal use in its intended medical setting.

**[0034]** Infection control in the hospital setting with newborn infants presents significant challenges. The infant-contact portions of a sophisticated, re-useable monitor system must be easily and reliably cleansed between uses. The present invention provides an easily cleaned, common infant clothing item and a wet-scrubbable sensor unit for use in direct contact with the infant patient's

skin. Common hospital-use soaps and disinfectants may be used directly on the surface of the water-immersible sensor unit. Gentle scrubbing with soft-bristled brush or washcloth is also tolerated by the surface hardness of the plastic coating.

**[0035]** Figure 1 diagrams the "Virtual Nursery" infant monitor system. The patient contact sensor 10 is mounted within a retaining pocket 20 of an infant undershirt 30 over the infant's heart. Half-plex (alternating one-way) radio communication 40 links this battery-powered sensor unit to a ceiling-mounted radio transceiver and computer network interface module 50. From the network interface module, the partially processed patient signal data is conveyed to a central computer network server and color graphic terminal 60 where final processing is performed and the information displayed. The patient contact sensors are re-charged, tested, and assigned to a specific baby by means of a network-connected sensor re-charge and test service module 70 prior to each use. Nurses directly caring for mothers and babies will carry "palm-top" handheld data management units 80, which communicate with the computer network via either infrared or radio transmission, and have audio output, enabling them to serve as alarm beepers and to remotely output an infant's chest sound, on request. Permanent paper records of the graphic diagrams and clinical record text are printed on paper 90 for the hospital chart, and archive computer media records 100 are also generated at the central station.

**[0036]** Figure 2 shows an optional embodiment of the present invention as an ambulatory infant monitoring system. The radio transceiver, computer network and server of the main embodiment are replaced by a small, portable, battery-powered data processing, display, and alarm output unit 110. This latter

unit may be worn by the infant's caregiver in such applications as ambulatory care of convalescing premature infants and monitoring infants at risk for Sudden Infant Death Syndrome (SIDS).

**[0037]** Figure 3 shows unique details of the preferred embodiment infant undershirt. The infant's shirt 30 has a band of stretch fabric 120 sewn around it; overlapping in the region of the infant's mid-chest. The free end of overlapping stretch fabric band is re-openably closed with mating Velcro™ strips 130a,b. The overlapped area of the fabric band is sewn to form a sensor unit retaining pocket 140. Light-opaque fabric 150 surrounds an opening in the inner surface of the undershirt, centered on the sensor unit pocket, to reduce ambient light levels immediately surrounding the pocket opening 160 for the sensor unit active face.

**[0038]** Figure 4 shows a cross-section of the sensor unit mechanism. The active sensor surface comprises a stethoscope diaphragm 200, with associated sound and temperature detectors. A piezoelectric transducer 210 is used to convert mechanical sound energy from the patient's chest into an electronic signal. An elastomer coupling post 220 mechanically links the center of the stethoscope diaphragm 200 with the center of the piezoelectric transducer 210. This mechanical impedance-matching coupling conserves mechanical energy, enhancing the efficient detection of low frequency heart- and lung-generated vibration and sound. A skin temperature sensor 230 is also adhered to the inner surface of the stethoscope diaphragm and connected by flexible circuit 240 to the sensor unit circuit.

**[0039]** Figure 5 shows the reflectance oximeter sensor of the present invention. Masking and chemical etching of metalization of the inner

stethoscope diaphragm surface creates an optically cleared area for transmission of reflected oximeter light to a linear array of detectors. Two Light Emitting Diode (LED) light emitters (300a = 595 nm, and 300b = 805 nm) are located over a light guide lens 310 which roughly collimates projected light into the patient's skin 320. Interaction of this light 330 with hemoglobin in mid-dermal arterioles variably absorbs the two alternately-projected wavelengths of light. A linear array detector receives the returned light, at a series of locations radial to the light emitters. Each of the preferred embodiment array's mirror-delimited condenser rod lenses 340 focus light returned through the transparent stethoscope diaphragm onto its respective light detector element 350. Thus, each illumination of an LED logs signal values corresponding to the reflected light at a series of distances radial to the LED light guide. Ambient light intensity readings are also logged immediately prior to, and following, each LED illumination. The sensor system transmits this light signal data to the remote data analysis system for processing, display, and alarm generation.

**[0040]** Figure 6 shows the preferred embodiment half-plex transceiver system of the present invention sensor unit. The sensor unit is intermittently polled by its corresponding data processing radio telemetry system. In response to each polling cycle, the sensor unit identifies itself by digital code, transmits its stored data frame, confirms error-free transmission, and logs off. A data communications antenna 500, battery 510, and battery re-charge power transmission antenna 520 are mounted outside a metallic cover 530 over the sensor unit circuitry. A plastic shell 540 is hermetically sealed over the metallic cover and to the metallic base frame 550. The resulting sealed outer surface

protects the internal components against liquid and abrasion when the unit is used, and when it is sanitized between patient uses.

**[0041]** In the preferred main embodiment, the "Virtual Nursery" infant monitor has four distinguishing features:

**[0042]** Continuous monitoring of infant skin temperature, breathing rate and depth, heart rate, and reflectance pulse oximetry;

**[0043]** Remote access, by means of radio transmission and computer network data communications, to infant biophysical signals and analyzed physiologic data;

**[0044]** Location, security, and physiologic status of the infant being monitored and cared for; and

**[0045]** Integration with hospital patient record database functions.

**[0046]** The present invention provides continuous, automated tracking of infant skin temperature, with or without an infant warming system. This allows clinical caregivers to monitor newborn infant temperature to assure safe and effective thermal management throughout the entire service period. Also included is the lead-less detection of infant breathing and heart rates by use of an electronic stethoscope. Remote computer processing of the electronic stethoscope signal derives the per-minute rates of these vital body functions. Also integrated with the electronic stethoscope and temperature sensor is a novel reflectance-mode pulse oximetry system.

**[0047]** Providing a radio transponder means of remote communication of the sensed data allows continuous physiologic tracking of newborn infant vital functions during their transition period. Being lead-less and automated, it offers minimal disturbance to the mother and infant and reduces the labor time and



cost for "checking routine vital signs." Digital radio transmission of chest sound also enables optional remote listening to infant chest sounds through hand-held data management units, or from a computer network central terminal.

**[0048]** Continuous tracking of the physical location of the monitored infant within the health care facility will be of benefit in assuring the security of the infant. It will also help hospital staff quickly identify where to find the baby immediately if an alarm condition occurs.

**[0049]** Including needed and novel services for all normal newborn infants in their transition period targets a significant and under-served market. The use of remote communications helps meet the public desire and expectation in this market for minimal appearance of technology intervention in the childbirth and convalescent care process. Eliminating the prior art "well baby nursery" floor space and the corresponding clinician and clerical staffing requirements, SRMC, with the assistance of the present invention technology, will also reduce the cost of providing childbirth health care services.

### **Operation of Invention**

**[0050]** A patient sensor unit is selected for use with a newly born infant. As one option, a bar code on the outer surface of the sensor unit is scanned by the nurse's hand-held data management unit, along with scanning of the mother's wristband bar code, to link the identities of mother and baby in the infant monitor computer system. As another option, a sensor unit can be placed in the charge/test module and polled for its identity on the central station computer and linked to the mother's identifier on the screen. As a third option, an identifying code on the sensor unit can be keyboard entered on either the

central computer terminal or the portable hand-held data management unit used by the nurse, and linked to a corresponding number from the mother's wristband. The selected sensor unit is then placed within the special holding pocket of the infant's undershirt when the newborn infant has been cleaned off, dried, and clothed.

**[0051]** When the electronic stethoscope function of the sensor unit detects infant heart sounds, it begins its data acquisition, processing, and polling-response transmission functions. Upon being polled by the monitor system computer network, or by a corresponding portable ambulatory data processing unit, frames of sensor data are transmitted from the patient sensor back to ceiling-mounted network node transceivers located in patient rooms and hallways, or to the portable processor. Each hospital transceiver/computer network node has its own identity code, which it combines with the received sensor data and relays to the network server. Each ambulatory set of two sensor units and data processing unit will have a unique identifier code to enable multiple monitored infants to share the same area or room without confusing data transmissions. The network server and central nursing station terminal, or the portable data processing unit, automatically analyzes the incoming data and creates numeric and graphic displays of the vital information regarding each infant being monitored by the system. Alarm outputs are triggered by the occurrence of out-of-normal-range data, specified combinations of values or trends, or decrease or loss of breath sound signal. In the hospital setting, these alarm outputs are displayed centrally and also relayed, by telemetry to the hand-held data management units carried by each nurse serving in the SRMC facility. Any nurse may respond by locating the infant, providing the needed intervention,

and silencing the alarm. The record system requires a notation of findings and responses given, and the coded identity of the hand-held unit adding this information to the record. The ambulatory embodiment similarly alarms, but only to its "own" data management unit's parameters and settings.

**[0052]** In the hospital embodiment, a permanent, summarized record of all monitored information derived from each infant, along with notations by nurses providing care, automatically becomes part of the permanent medical record in both print and computer media for later analysis. A secured Intranet and Internet channel is provided for attending physicians and system administrators to access patient data from alternate remote sites. The ambulatory system provides a telephone modem connection to allow transmission of stored data to the attending physician for analysis and advice.

**[0053]** Physical location tracking and security of each infant is provided as a function of the limited range and coded identity of the sensor units and the radio transceivers installed throughout the hospital-based system. Each ceiling-mounted interface module defines a unique location zone. The radio signals communicated between patient contact sensor units and these nodes penetrate walls very poorly. Therefore, the identified interface module relaying code-identified infant patient data to the server defines the physical location of that infant. The ambulatory system only relates one of its set of two identically-coded sensor units to a matching data processing unit. Loss of infant-derived data signal, as with removal of the sensor unit from contact with the infant, will trigger an alarm. Loss of response to polling for a sensor unit's data frame will define the exit of the baby and its assigned sensor from the SRMC perimeter in the hospital setting, or the range perimeter of the ambulatory system, and trigger a

security alarm. The last valid hospital location of the infant will be displayed on the central terminal to assist in immediately tracking the loss of response or possible infant abduction.

**[0054]** Following use with one patient, the sensor unit is removed from the undershirt, scrubbed clean with disinfectant solution, rinsed, and wiped dry. It is then placed in a battery re-charger and self-test module, in the hospital system, or into a re-charge and self-test fixture within the portable data processor unit, to prepare for the next patient use.

### **Conclusion, Ramifications, and Scope of Invention**

**[0055]** The unique objects for safe and clinically effective remote monitoring of newborn infants have been met by the present invention. The advantages gained by the present system integration approach are a result of a balanced application of existing technical capabilities on several fronts, accommodation of economic realities, and close attention to emotional and social needs.

**[0056]** The emotional and social ramifications of the present invention are its most noticeable benefits. Families will be able to keep their well babies in the mother's room, as is most commonly desired, during the socially important first few hours of the baby's life. Parent training and reassurance can be provided in an uninterrupted, private, and calm venue. Repeated, routine manual vital signs checking of the infant, and manual data recording, is eliminated. Simple, inexpensive, thermostatically regulated infant warmer mattress beds may be used in the mother's room during the infant's transition period, in lieu of expensive and sophisticated servo-controlled, NICU-style infant warming

equipment in a physically separate “admission,” or “well-baby” nursery some distance from the mother’s room.

**[0057]** While the initial impetus for the present invention is an improved social environment for new families, a wealth of new and objective data will be automatically captured, in computer format, for large-scale analysis. A greater understanding and appreciation for normal to slightly abnormal infant physiology and developmental changes are possible additional benefits. This improved understanding could lead to improvements in outcome through focused procedural adjustments.

**[0058]** The infant-specific features and operating parameters of the integrated sensor system of the present invention may represent advancements that can also be applied to monitoring sick infants and, possibly, larger children and adults, and in veterinary medicine and surgery. The telemetry features of the hospital installation offer future opportunities to develop newborn intensive care equipment in an in-hospital-mobile format to also allow visits of sick babies to bedridden mothers.

**[0059]** Other alternative applications will become evident to the user as experience accumulates. Among these alternative applications, but not to be considered as excluding any other possible application, are 1 ambulatory monitoring of infants recently discharged from intensive care and 2 infants deemed at risk for Sudden Infant Death Syndrome (SIDS). Adult 3 and older child patients 4 who need a combination of security locator and basic physiologic monitoring to help enable independent living, could also benefit from the remote communications features provided by this invention. Finally, 5 athletes could

use the ambulatory system to log physiologic responses to their exercise or performance efforts.

**[0060]** In compliance with the statute, the invention has been described in language more or less specific as to structural and methodical features. It is to be understood, however, that the invention is not limited to the specific features shown and described, since the means herein disclosed comprise preferred forms of putting the invention into effect. The invention is, therefore, claimed in any of its forms or modifications within the proper scope of the appended claims appropriately interpreted in accordance with the doctrine of equivalents.